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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/808,041	03/24/2004	Roman M. Chicz	08191-008004	6563

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EXAMINER	
ZHOU, SHUBO	
ART UNIT	**PAPER NUMBER**
1631	

DATE MAILED: 04/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/808,041	CHICZ ET AL.	
	Examiner	Art Unit	
	Shubo (Joe) Zhou	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10-14 and 17-20* is/are pending in the application.

4a) Of the above claim(s) *10-13 and 17-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *06 July 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/8/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Preliminary Amendments

1. Applicants' preliminary amendments to the claims and specification filed 3/24/04 are acknowledged and entered.

Consequently, claims 1-9, 15-16, and 21-42 have been canceled and claims 10-14 and 17-20 are currently pending.

Restriction/Election Requirement

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 10-13, drawn to a method of generating a reproducible ligand profile for a cell type involving using a first sample and a second sample for detecting pluralities of ligands bound to a same multi-ligand binding receptor in each of the samples, classified in class 702, subclass 19.

II. Claim 14, drawn to a method for generating a ligand profile for a cell type involving using one sample for detecting pluralities of ligands bound to a first type of multi-ligand binding receptor and a second type of multi-ligand binding receptor, classified in class 702, subclass 19.

III. Claims 17-20, drawn to a method for comparing a first cell sample to a reference cell sample, classified in class 702, subclass 19.

The inventions are distinct, each from the other because of the following reasons.

Inventions of group I and group II or III are directed to related but distinct processes. The related inventions are distinct if the inventions as claimed are mutually exclusive; are not obvious variants; and are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the methods of groups I-III are related because they all involve obtaining ligand profiles for multi-ligand binding receptors. However, the methods are mutually exclusive, not obvious variants and have different modes of actions, functions and effects. Group I involves using a first sample and a second sample of a cell type for detecting a plurality of ligands bound to the same multi-ligand binding receptor to generate a ligand profile for the receptor in each of the two samples, and the two profiles together represent the ligand profile for the cell type. Group II, however, involves using one sample for detecting a plurality of ligands bound to two types of receptors: a first type of multi-ligand binding receptor and a second multi-ligand binding receptor in the same sample of a cell type to generate a ligand profile for the cell type. Group III, on the other hand, involve generating a ligand profile for a multi-ligand binding receptor for a cell type and comparing the profile with a reference ligand profile representing a second set of polypeptide ligands extracted from the same type of receptor of a reference cell sample in order to identify differences or similarities between the first cell sample and the reference cell sample. It is thus clear that the three methods use distinct steps and produce distinct results and are mutually exclusive. Therefore, the inventions of groups I-III are distinct.

Because these inventions are distinct for the reasons given above, they have acquired a separate status in the art. The search required for the groups are not co-

extensive because each group requires a different search strategy due to their comprising different method steps and producing different results, as well as the unique features in each of the groups as set forth above. Thus, there would be serious search burden if all groups were examined together. Therefore, the restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

3. During a telephone conversation with Jack Brennan on 3/8/06, a provisional election, without traverse, was made to prosecute the invention of group II (claim 14). Affirmation of this election must be made by applicant in replying to this Office action. Claims 10-13 and 17-20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Sequence Rules Compliance

4. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). Such sequences are present in Figures 5B and 5C. However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 because (1) while a paper copy and a computer readable form of a Sequence Listing are provided, a statement under 37 CFR 1.821(f) has not been filed; (2) the sequences in Fig. 5B and 5C are not followed by a sequence identifier (SEQ ID NO:X); and (3) it is noted that a sequence "[RP]V[NR][KQ]FSDR", which appears to be encompassed by the definitions for amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2), is not listed in the Sequence Listing filed 3/24/04. The sequence, which includes "FSDR," does not appear to be a fragment of any of the sequences of SEQ ID NOS: 1 and 2. Applicants are given the same response time regarding this failure to comply as that set forth to respond to this Office action including providing a paper copy, a computer readable form of a new Sequence Listing containing this sequence, as well as a statement under 37 CFR 1.821(f). Applicants are reminded that it is required that SEQ ID Nos be amended into the specification at each sequence, and that when a sequence is presented in a drawing regardless of the format or the manner of presentation of that sequence in the drawing, the sequence must still be included in the Sequence Listing and the sequence identifier must be used, either in the drawing or in the Brief Description of the Drawings. Failure to comply with these requirements may result in ABANDONMENT of the application under 37 CFR 1.821(g).

Drawings

5. The amended drawings filed 7/6/04 are acknowledged. The amendment, however, does not comply with 37 CFR 1.121(d) because (1) the amended drawings do not have the header of "Replacement Sheet" on each amended sheet of the drawings, and (2) changes to the drawings have not been "explained, in detail, in either the drawing amendment or remarks section of the amendment paper," as required by 37 CFR 1.121(d). While it is noted that the amended drawings are filed in response to an Office letter, the amendment still needs to comply with 37 CFR 1.121(d).

Specification

6. The specification is objected to because of the following:

The title of the invention is not descriptive. The claimed invention is drawn to a method for generating a ligand profile for a given cell type. The current title, however, is directed to "profiling and cataloging expressed protein tags." A new title is required that is clearly indicative of the invention to which the elected claim is directed.

Applicant is reminded of the proper content of an Abstract of the Disclosure. In chemical patent abstracts for compounds or compositions, the general nature of the compound or composition should be given as well as its use, *e.g.*, "The compounds are of the class of alkyl benzene sulfonyl ureas, useful as oral anti-diabetics." Exemplification of a species could be illustrative of members of the class. For processes, the type reaction, reagents and process conditions should be stated, generally illustrated by a single example unless variations are necessary. In the instant case, the claims are drawn to a method for generating a ligand profile for a given cell type, whereas the Abstract on

page 117 of the specification does not even mention such a method. Appropriate revision of the content of the abstract is required on a separate sheet.

It appears that trademarks are used in this application, such as GENBANK on page 13 and SEPHADEX on page 103. Trademarks should be capitalized wherever they appear and be accompanied by the generic terminology. Applicants are requested to review the entire specification to make appropriate corrections for all trademarks. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

It appears that the first letter of "hsp70" in line 28 of page 102 and line 3 of page 103 in the specification should be capitalized due to being present at the beginning of a sentence.

Appropriate correction is required.

Claim Rejections-35 USC § 112

7. The following is a quotation of the **second** paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claim 14 is rejected under 35 U.S.C. 112 , second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The preamble of claim 14 recites "generating a ligand profile for a given type of cell." Note the recited singular "profile" for the cell type. The body of the claim, i.e. steps (a) through (e), however, generates two profiles: " a first profile," recited in line 1 of step

(e), and "a second profile," recited in line 2 of step (e). It is not clear what is the singular "ligand profile" for the given cell type as recited in the preamble: the first profile, the second profile, the combination thereof, or the difference thereof, or else?

Clarification of the metes and bounds of the claims is requested.

Claim Rejections-35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claim 14 is rejected under 35 U.S.C. § 102(b) as being anticipated by Chicz et al. (IDS document: Immunology Today, Vol. 15, pages 155-160, 1994).

Claim 14 is drawn to a method comprising providing a sample of lysate of a type of cell which comprises a plurality of ligands bound to a first type of multi-ligand receptor and a plurality of ligands bound to a second type of multi-ligand receptor, isolating the receptors from the sample, separating the pluralities of ligands from the receptors, fractionating the ligands and generating a profile of ligands bound to the first receptor and a profile of ligands bound to the second receptor.

Chicz et al. disclose a method of "serial epitope-detecting system" for MHC molecules, which are multi-ligand receptors. The method comprises providing an extract containing MHC-peptide complexes from antigen-presenting cells (APCs) grown in the presence or absence of pathogen-derived extract (PDE), loading the extract comprising the MHC-peptide complexes onto a column of matrix comprising one of allotype specific monoclonal antibodies against the specific MHC molecules thereby isolating the

receptors, separating the bound peptides with the receptors under alkaline conditions, etc., fractionating the peptides through size-exclusion chromatography, solid phase peptide extraction, microcapillary reversed-phase chromatography, etc., which peptides are eluted to mass spectrometer, each being assigned a mass/time distinction. A ligand profile for each receptor is generated in the presence or absence of PDE, and a ligand profile is generated to identify unique peptides present only in the PDE+ population can also be generated by a subtractive algorithm. Thus, the peptides are fractionated based at least on size and mass. The MHC receptors analyzed are at least two types including HLA-A, HLA-B, HLA-C, HLA-DR, HLA-DQ, and HLA-DP. See page 158, left column, especially Box 2, and right column, especially "Serial epitope-detection system" and page 157, Figure 1 and legend thereof.

Conclusion

11. No claim is allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shubo (Joe) Zhou, whose telephone number is 571-272-0724. The examiner can normally be reached Monday-Friday from 8 A.M. to 4 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D., can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Patent Analyst Tina Plunkett whose phone number is (571) 272-0549.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Shubo (Joe) Zhou, Ph.D. 4/16/06

Patent Examiner